

PATENT  
USSN 09/721,506  
002616US; 018-210c

### REMARKS

This paper is responsive to the Office Action dated January 11, 2006, which has been made final.

Claims 75-78, 80, 83-86, 88, 91-94, 96, and 101-104 were previously pending. Upon entry of this amendment, claims 83-86, 88, 91-96, 101, and 103-104 are newly cancelled, being replaced by new claims 105-108, which fall within the group under examination. Accordingly, claims 75-78, 80, 102, and 105-108 are pending, with claim 80 being withdrawn from examination.

Further consideration and allowance of the application is respectfully requested.

### Interview Summaries

The undersigned is grateful to Examiner Sisson for cordial and helpful discussions regarding this application by telephone on February 14 and February 21, 2006. The amendments and remarks that were proposed during the interviews are incorporated into this response.

However, the undersigned is surprised that one of the Interview Summaries prepared by the Office encloses a copy of the claim sets sent *for discussion purposes only* to the Examiner's personal fax number, each page of which explicitly requests that it not be entered into the file. The claim sets were prepared with a view to promoting discussion, and not for any other purpose. They do not represent by implication or otherwise the scope of subject matter that the owners of this invention regard as patentable, and should not in any way be considered to constrain equivalents to the claimed invention that are covered by the pending claims.

The undersigned also respectfully puts forward the following corrections to the comments made in the Interview Summary prepared by the Office that is dated February 23, 2006:

- Contrary to what is indicated in the Summary, Dr. Schiff did not indicate that the application provided no sequence data for variants. In fact, Dr. Schiff explicitly referred to alternative natural variants of hTERT (which are described *inter alia* in Example 9). Although not discussed during the interview, the specification also exemplifies a number of variants of hTERT made by mutation of SEQ. ID NO:2 (Example 16). Dr. Schiff reiterated during the interview applicants' position that the specification fully describes and enables the making and using of various hTERT variants, including but not limited to the scope previously claimed in this application.

PATENT  
USSN 09/721,506  
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- Dr. Schiff indicated that the degree of identity between the full-length mouse TRT sequence and the full-length human TRT sequence was substantially lower than 80%. However, he made no assertion during the interview with respect to the identity of human TRT with the TRT of other particular mammals. To the extent the Office deems this matter pertinent for examination of this application, the Office is invited to do its own comparative sequence analysis.

These corrections notwithstanding, applicants appreciate the progress made in this application. The claims are now amended to focus on embodiments of the invention that are of current commercial interest. The amended claims are believed to be in condition for allowance, which is respectfully requested.

Rejection under 35 USC § 112 ¶ 1

The claims under examination stand rejected as failing to comply with the written description requirement of § 112 ¶ 1. The new remarks in the Office Action indicates that the specification as filed does not provide an adequate written description of the  $4.39 \times 10^{14}$  possible 100-mers covered by some of the claims.

Applicants have not checked the calculations made in the Office Action, because the standard for complying with § 112 ¶ 1 does not depend directly on the number of species actually covered. There is no doubt that the application fully describes the prototype SEQ. ID NO:2, and also contemplates variants of the prototype sequence defined either by percentage of identity over a specified number of amino acids, or by the hybridization properties of nucleic acids that encode the variants. At the time of filing of the priority application, a wide variety of techniques were available for modifying the prototype sequence by addition, deletion, or mutation in a site-specific manner, or by random mutagenesis, and the user could easily screen variants for telomerase function by high throughput screening using the assay systems detailed in the specification. Thus, the skilled reader would appreciate that the inventors had full possession of the claimed genus of hTERT variants, and could readily identify which variants were functional without undue experimentation.

It is applicants position that the claims as previously presented met all the requirements of 35 USC § 112 ¶ 1, in accordance with the Written Description Guidelines promulgated by the Office on March 7, 2000.

PATENT  
USSN 09/721,506  
002616US; 018-210c

Nevertheless, to simplify consideration of these matters and to focus coverage on embodiments of the invention of current commercial interest, the claims are herein amended to cover sequences that are at least about *95% identical over the full length of SEQ. ID NO:2*, and equivalents of such variants for which coverage is allowed in accordance with the relevant case law. The amendments are made without prejudice. Applicants reserve the right to reintroduce claims to other embodiments of the invention in this or any related application at a later time.

Claims 75-78 and 102 further require that the claimed fragments have *telomerase catalytic activity when complexed with a telomerase RNA*, as can be determined *inter alia* by the telomerase enzyme activity assays detailed in the specification.

Withdrawal of the § 112 ¶ 1 rejection of these claims is respectfully requested.

Claims 105-108 replace the cancelled claims, and recite an alternative function for the claimed fragments: specifically, the property of being *immunogenic for an antibody against hTERT*. The use of SEQ. ID NO:2 to make antibody against hTERT is described in the specification, for example, in U.S. Patent 6,166,178 (of which this application is a continuation) in cols. 71-75 and col. 89. The skilled reader will appreciate that polypeptides of 100 amino acids or more in length typically have a number of different Class I and Class II epitopes, and will be capable of eliciting specific antibody in a suitable host.

Claim 106 refers to a particular subfragment of the full-length hTERT protein designated SEQ. ID NO:13. This application is a continuation-in-part of U.S. Patent 6,261,836, and incorporates it by reference. The '836 patent lists the same hTERT fragment as SEQ. ID NO:67. The '836 patent specifically refers to the use of this fragment for obtaining specific antibody at col. 8, lines 30-36.

Claim 107 refers to the rest of SEQ. ID NO:2 not contained in SEQ. ID NO:13. This is in accordance with MPEP § 2173.05(i), which states: "If alternative elements are *positively* recited in the specification, then they may be explicitly *excluded* in the claims: See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 194 (CCPA 1977) ('[the] specification, having described the whole, necessarily described the part remaining.')."

Accordingly, claims 105-108 also meet the patentability requirements of 35 USC § 112 ¶ 1.

PATENT  
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#### Double patenting

Certain claims stand provisionally rejected for double patenting in view of what is claimed in U.S. Patent 6,337,200, USSN 09/438,486 (now U.S. Patent 6,927,285) and USSN 10/054,295 (now U.S. Patent 6,921,664). Certain claims stand provisionally rejected for double patenting in view of what is claimed in USSN 09/721,477, USSN 10/044,692, and USSN 10/877,124.

Applicants respectfully disagree, because any overlap with the cited cases will depend on the nature and scope of claims in the present application remaining when prosecution is otherwise concluded. Double patenting will not apply to claims having a scope that excludes obvious variants of the subject matter claimed in the other applications. Double patenting will also not apply to applications that are less advanced in prosecution. Applicants undertake to reassess and address any remaining double patenting issues promptly upon indication of what claimed subject matter in this application is otherwise allowable.

The Examiner is reminded under 37 CFR § 1.56 that there are other patents and applications pending that relate to telomerase. These include the patents and applications listed in the Appendix that follows. Recent developments include issuance of U.S. Patent 7,005,262, and allowance of USSN 09/843,676 and USSN 09/990,080.

#### Request for Interview

Applicants respectfully request that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, the undersigned hereby request an interview by telephone.

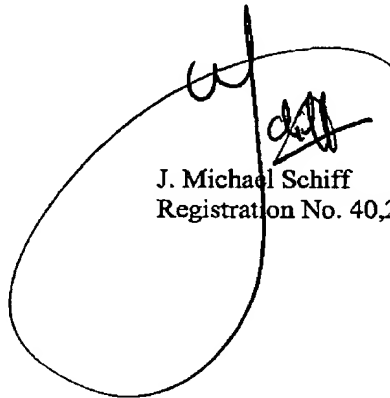
PATENT  
USSN 09/721,506  
002616US; 018-210c

Fees Due

No fee is believed payable with respect to the entry and consideration of this paper.

Nevertheless, in the event that the Patent Office determines that an extension of time or any other relief is required for further consideration of this application, applicants hereby petition for such relief, and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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